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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,827	01/15/2004	Michael R. Rosen	P4463US02	5518
31856	7590	08/17/2011		
Evans & Molinelli PLLC			EXAMINER	
P.O. Box 7027			SINGH, ANOOP KUMAR	
Fairfax Station, VA 22039				
		ART UNIT	PAPER NUMBER	
		1632		
		MAIL DATE	DELIVERY MODE	
		08/17/2011	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/757,827

Applicant(s)

ROSEN ET AL.

Examiner

ANOO P SINGH

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 August 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
 NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 20, 49, 51, 57, 59 and 65-71.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Anoop Singh/
Primary Examiner, Art Unit 1632

Continuation of 3. NOTE: The proposed amendment to independent claims 20 and 65 that include a negative limitation "wherein the MSC is not incorporated with a nucleic acid which encodes a connexin" raises new issues that requires new consideration for art purposes. The amendments with new limitations changes the breadth of proposed claims and therefore requires new combination of art. Therefore, proposed claim amendments have not been entered. .

Continuation of 11. does NOT place the application in condition for allowance because: The Examiner maintains the rejection of claims 20, 49, 51, 57, 59, 65-70 and 71 for the reasons of record. To the extent arguments apply to the pending claims, applicant arguments filed on 06/08/2011 have been fully considered but they are not fully persuasive, because the proposed claim amendments have not been entered and require new consideration as stated above. The rejection of claims 20, 49, 51, 57, 59, 65-70 and 71 are maintained for the reasons of record as applicant's arguments all rely on the not entered claim amendments.

Claims 20, 49, 51, 57, 59, 65-70 and 71 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Feld et al (US patent no 7294333, dated 11/13/2007, filed on 10/20/2000), Lee et al (Molecular Therapy, 2001, 857-866, IDS, hereafter Lee 1), Lee et al. (USP 7,494,644, dated 2/24/2009, effective filing date 11/7/2002, art of record, hereafter Lee 2), and Qu et al (Circulation res. 2001, 89:e8-14, IDS) for the reasons of record. The rejection of claims are maintained as applicant's arguments (MSC is not incorporated with a nucleic acid encoding connexin) all rely on the not entered claim amendments.

Applicant argues that Wang 2000 reference provides only suggestive morphological data that injected stem cells form gap junctions with myocytes. It does not provide proof that there is functionality, i.e. functioning ion channels between stem cells and myocytes that can conduct current or transfer molecules (as evidenced, for example by dye transfer).

Such is not persuasive because Wang reference was discussed during telephone interview only in response to applicants' argument that there is no prior art that teaches MSC form gap junction with cardiomyocyte. Wang et al teaches positive staining for connexin 43 indicates the formation of gap junctions, which suggests that MSC, as well as native cardiomyocytes, are connected by intercalated disks. To the extent, Wang teaches formation of gap junction, the reference may be pertinent to the proposed claims. Applicants' selective argument of Lee teaching transfecting MSC with connexin to achieve gap junction has no relevance to the teaching of Wang because even instant specification contemplate using MSC with or without transfection of connexin in the claimed method. One of ordinary skill in the art would expect improved gap junction formation when MSC is transfected with connexin, but that does not negate the fact that Wang specifically teach formation of gap junction between untransfected MSC and cardiomyocytes as evident from positive staining for connexin 43 (see figure 5).